

Date of Deposit: March 10, 2008

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Maggi, et al.
APPLICATION No. : 10/507,344 EXAMINER : Hasan Syed Ahmed
FILING DATE : September 10, 2004 ART UNIT : 1615
FOR: THERAPEUTIC SYSTEM FOR THE CONTROLLED RELEASE OF ACTIVE
INGREDIENTS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

COPY

DECLARATION UNDER 37 CFR § 1.132 OF UBALDO CONTE

I, Ubaldo Conte, of Via Treviglio, 6-21052 Busto Arsizio, Italy, declare and state:

1. I have read and understand the subject matter described and claimed in the instant application, United States Patent Application Serial No. 10/507,344 filed September 10, 2004 ("the '344 application"), entitled "Therapeutic System for the Controlled Release of Active Ingredients."

2. I have read and understand the Office Action mailed on September 10, 2007 understand that claims 1, 2, 4, 5, and 8-25 are rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,650,169 ("Conte").

3. I am a co-inventor of the '344 application.

4. I am also a co-inventor of Conte.

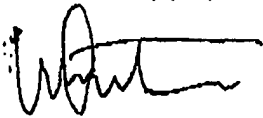
5. I make this Declaration to establish that the process by which the therapeutic tablet system described in claims 1, 2, 4, 5 and 8-25 are made imparts function and structural limitations to this product.



6. I declare and state that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system of claims 1, 2, 4, 5 and 8-25 greater stability than the tablets taught in Conte. The incision(s) delimited film coating of the tablet of claims 1, 2, 4, 5 and 8-25 remains intact before contact with aqueous fluids. Thus, the laser generated incisions of the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration. Whereas the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient exposed. I submit that the tablet of the claimed invention is different than the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process.

7. I also makes this Declaration to establish that the process of making the therapeutic tablet system of claims 1, 2, 4, 5 and 8-25 gives the system a more advantageous release profile for constant steady release of drug than the tablets taught in Conte. The graphs in Exhibit A, submitted herewith, illustrate that the tablets in Conte, on average, initially release over 30% of the active ingredient and after the initial release, the release profile tends to flatten out until a subsequent release occurs. In contrast, the claimed tablet has a substantially linear drug release rate, in general, the initial amount of the drug released is below 20%. The incision(s) on the claimed tablet in an impermeable coating that fully covers the active ingredients, clearly alters the release profile, with a pre-determinable and programmable release rate compared to the release profiles of Conte.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.



Ubaldo Conte

March 20, 2008

Date